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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/664,371	09/17/2003	Jorge L. Orbay	HAN-022	4572
36822 7590 01/05/2010 GORDON & JACOBSON, P.C. 60 LONG RIDGE ROAD SUITE 407 STAMFORD, CT 06902				
EXAMINER RAMANA, ANURADHA				
ART UNIT		PAPER NUMBER		
3775				
MAIL DATE		DELIVERY MODE		
01/05/2010		PAPER		

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/664,371

Applicant(s)

ORBAY, JORGE L.

Examiner

Anu Ramana

Art Unit

3775

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02 October 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 37, 38, 40-43, 45-55, 58, 59, 61 and 65-69 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 59 and 61 is/are allowed.
- 6) ☒ Claim(s) 37, 38, 40-43, 45-55, 58 and 65-69 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 13 April 2009 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-940)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Drawings

The drawings filed on April 13, 2009 are objected to because Fig. 3A seeks to introduce new matter, not supported by Applicant's disclosure, as originally filed. Please refer to the detailed discussion in the objection to the specification below. Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Specification

The amendment filed on April 13, 2009 is objected to under 35 U.S.C. 132(a) because it introduces new matter into the disclosure. 35 U.S.C. 132(a) states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows. "Each alignment hole 152 is located between two immediately adjacent peg holes 134 with each alignment hole being located entirely within a boundary that may be defined by a tangent T₁ to a proximalmost point on circumferences of the two immediately adjacent peg holes, a tangent T₂ to a distalmost point on the circumferences of the two

immediately adjacent peg holes." Also, "The proximal boundary line may alternatively be defined as a line X_1 between the distalmost points of the two immediately adjacent peg holes" is deemed to be new matter. Tangent T_1 does not extend between the proximalmost points on the circumferences of two immediately adjacent peg holes. Also, tangent T_2 does not extend between the distalmost points on the circumferences of two immediately adjacent peg holes. Line X_2 does not extend between the distalmost points of two immediately adjacent peg holes. Rather, line X_2 extends between the distalmost points of the heads of pegs placed in immediately adjacent peg holes.

The language regarding "a tangent T_3 to a lateralmost point on the circumference of a medialmost of the immediately adjacent peg holes, and a tangent T_4 to a medialmost point on the circumference of a lateralmost of the two immediately adjacent peg holes" is not deemed to be new matter.

Applicant is required to cancel the new matter in the reply to this Office Action.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 37-38, 40-43, 45-55, 58 and 65-69 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The recitation in claim 37, lines 17-20; claim 48, lines 16-18; and claim 65, lines 13-15 seeks to introduce new matter.

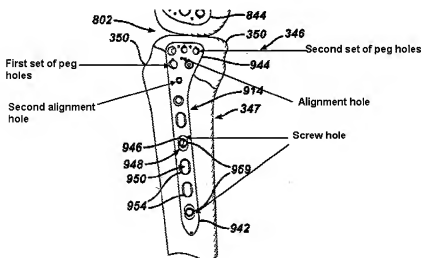
Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 37-38, 40-43, 45-51, 53-55, 58, and 65-69 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wack et al. (US 2004/0030339 A1) in view of Procter et al. (US 5,527,311).

Wack et al. disclose a plate 914 defining a first set of peg holes structurally adapted to engage a threaded head of a fixation peg and at least one non-threaded alignment hole or k-wire hole sized to receive a k-wire, the alignment hole having a second small diameter relatively smaller than each of the peg holes in the first and second sets (Figs. 20-22 and paras [0118]-[0162]). See a portion of Fig. 20 marked up to show features of Applicant's invention below.



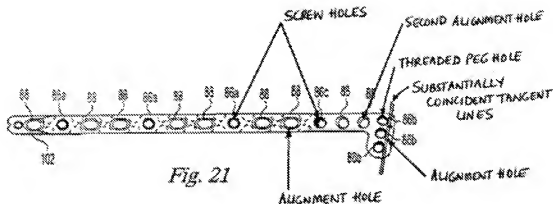
Procter et al. teach various arrangements of alignment holes in a bone plate to facilitate shaping of the bone plate wherein a particular arrangement involves placing alignment holes entirely between the boundaries (as claimed) of adjacent peg holes (Fig. 5).

Therefore, it would have been obvious to a person of ordinary skill in the art at the time the invention was made, to have tried an arrangement wherein the alignment holes are entirely between claimed boundaries of adjacent peg holes in the Wack et al. plate, since there are a finite number of identified, predictable potential solutions, or arrangement of holes, and one of ordinary skill in the art could have pursued the known options within his or her technical grasp with a reasonable expectation of success.

Regarding claim 47, it would have been an obvious matter of design choice to a person of ordinary skill in the art at the time the invention was made to have provided $n-1$ alignment holes for n peg holes, since Applicant has not disclosed that providing a specific number of alignment holes between a specific number of peg holes provides an advantage. One of ordinary skill in the art, furthermore, would have expected the Wack et al. bone plate and applicant's invention, to perform equally well with either $n+1$ alignment holes for n peg holes or the claimed " $n-1$ alignment holes for n peg holes" because both numbers of alignment holes would perform the same function of provisionally fixing the plate to the bone.

Claims 37-38, 40-41, 45-48, 51, and 53-55 are rejected under 35 U.S.C. 103(a) as being unpatentable over Weaver et al. (US 6,623,486) in view of Procter et al. (US 5,527,311).

Weaver et al. disclose a bone fixation plate 80 including: a head angled relative to the shaft; the head portion defining a first set of threaded holes 86b; alignment holes much smaller in diameter than the threaded holes for provisional fixation of the bone plate; a second alignment hole 88; and a plurality of screw holes 86a in the shaft of the bone plate (Figs. 20-26, col. 6, lines 58-67 and col. 7, lines 1-17). See marked up Fig. 21 from Weaver et al. on the following page.



Weaver discloses all elements of the claimed invention except for an alignment hole located entirely between two immediately adjacent peg holes.

Procter et al. teach various arrangements of alignment holes in a bone plate to facilitate shaping of the bone plate wherein a particular arrangement involves placing alignment holes entirely between the boundaries (as claimed) of adjacent peg holes (Fig. 5).

Therefore, it would have been obvious to a person of ordinary skill in the art at the time the invention was made, to have tried an arrangement wherein the alignment holes are entirely between claimed boundaries of adjacent peg holes in the Weaver et al. plate, since there are a finite number of identified, predictable potential solutions, or arrangement of holes, and one of ordinary skill in the art could have pursued the known options within his or her technical grasp with a reasonable expectation of success.

Claim 52 is rejected under 35 U.S.C. 103(a) as being unpatentable over Wack et al. and Procter et al. further in view of Klaue et al. (US 5,002,544).

The combination of Wack et al. and Procter et al. disclose all elements of the claimed invention except for the specific shape of the hole.

Klaue et al. teach providing a hole in a bone plate wherein the hole has a wider cross section toward the bone application side of the bone plate in order to permit the

insertion and gliding of inclined screws or fixation members (Fig. 5 and col. 2, lines 59-68).

Accordingly, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have provided holes having a cross section as taught by Klaue et al. in the bone plate of the combination of Wack et al. and Procter et al., to permit the insertion and gliding of inclined fixation members.

The combination of Wack et al., Procter et al. and Klaue et al. discloses all elements of the claimed invention except for the shape of the hole at the upper surface of the bone plate being circular and the shape of the hole at the bottom surface of the bone plate being oblong. It would have been an obvious matter of design choice to one skilled in the art at the time the invention was made to have constructed the hole with the claimed cross sectional shapes at the upper and lower surfaces of the bone plate, since applicant has not disclosed that this solves any stated problem or is anything more than one of numerous shapes or configurations a person of ordinary skill in the art would find obvious for the purpose of providing a hole in a bone plate. In re Dailey and Eilers, 149 USPQ 47 (1966).

Claim 52 is rejected under 35 U.S.C. 103(a) as being unpatentable over Weaver et al. and Procter et al. further in view of Klaue et al. (US 5,002,544).

The combination of Weaver et al. and Procter et al. disclose all elements of the claimed invention except for the specific shape of the hole.

Klaue et al. teach providing a hole in a bone plate wherein the hole has a wider cross section toward the bone application side of the bone plate in order to permit the insertion and gliding of inclined screws or fixation members (Fig. 5 and col. 2, lines 59-68).

Accordingly, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have provided holes having a cross section as taught by

Klaue et al. in the bone plate of the combination of Weaver et al. and Procter et al., to permit the insertion and gliding of inclined fixation members.

The combination of Weaver et al., Procter et al. and Klaue et al. discloses all elements of the claimed invention except for the shape of the hole at the upper surface of the bone plate being circular and the shape of the hole at the bottom surface of the bone plate being oblong. It would have been an obvious matter of design choice to one skilled in the art at the time the invention was made to have constructed the hole with the claimed cross sectional shapes at the upper and lower surfaces of the bone plate, since applicant has not disclosed that this solves any stated problem or is anything more than one of numerous shapes or configurations a person of ordinary skill in the art would find obvious for the purpose of providing a hole in a bone plate. In re Dailey and Eilers, 149 USPQ 47 (1966).

Claims 65-69 are rejected under 35 U.S.C. 103(a) as being unpatentable over Weaver et al. and Procter et al. further in view of Putnam et al. (US 5,586,985).

The combination of Weaver et al. and Procter et al. disclose all elements of the claimed invention except for the use of K-wires for provisional fixation of bone plate 80.

Putnam et al. teach the use of K-wires for provisional or temporary fixation of a bone plate to a bone surface (col. 7, lines 63-67 and col. 8, lines 1-14).

Accordingly it would have been obvious to one of ordinary skill in the art at the time the invention was made to have utilized K-wires as taught by Putnam et al. to temporarily fix the bone plate of the combination of Weaver et al. and Procter et al. since it was well known in the art to use K-wires to temporarily or provisionally fix a bone plate to bone.

Response to Arguments

Applicant's arguments filed have been fully considered but are not persuasive with respect to the rejections under 35 USC 103(a) over Weaver et al. in view of Procter et al.

The smaller circular holes 18 of Procter et al. are located within the claimed boundaries (see Fig. 5).

Further, Procter et al. was used by the Examiner to demonstrate various possible arrangements of alignment holes, not to place additional holes between the screw holes of Weaver et al.

Allowable Subject Matter

Claims 59 and 61 are allowed.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anu Ramana whose telephone number is (571) 272-4718. The examiner can normally be reached Monday through Friday between 8:00 am to 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thomas Barrett can be reached at (571) 272-4746. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

AR
January 1, 2009

/Anu Ramana/
Primary Examiner, Art Unit 3775